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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/683,692	10/09/2003	Jean Pierre Giraud	62357.012901(CSP-0073US)	9932

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EXAMINER	
NGUYEN, HUONG Q	
ART UNIT	**PAPER NUMBER**
3736	

DATE MAILED: 04/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 10/03)

18

Office Action Summary	**Application No.** 10/683,692	**Applicant(s)** GIRAUD, JEAN PIERRE	
	Examiner Helen Nguyen	**Art Unit** 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 April 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) *1-5 and 15-17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6-14* is/are rejected.

7)☒ Claim(s) *7,10-12* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *24 March 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/13/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election **without** traverse of **Claims 6-14** in the reply filed on 4/4/2006 is acknowledged. **Claims 1-5, 15-17** are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions.

Priority

2. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged, namely, priority to provisional application 60/417201, filed on 10/9/2002.

Information Disclosure Statement

3. The information disclosure statement (IDS) submitted on 12/13/2004 is/are acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

4. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been

considered. These refer to US Pat No. 5494562, 5202261, 6192891, 6127852 disclosed on p.11 of the specification.

Drawings

5. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the subject matter of **Claims 6-14** must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

6. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

7. The amendment filed on 3/24/2004 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. Please see MPEP 608.04(b). The added material which is not supported by the original disclosure is as follows:

> Figures 9A, 10A-D, and 18 and the corresponding description of the drawings and detailed descriptions:
>
> "Figure 9A is perspective view showing another arrangement for linking a plurality of lancets and test strips."
>
> "Figure 10A is a perspective view showing another arrangement of a cassette for storing lancets and or test strips, delivering them for penetration into the person's body, and analyzing the sample taken from the person."
>
> "Figure 18 is a perspective view showing an integrated lancet and test strip that could be used for immediate testing or transported to another location for testing."
>
> "Figure 9a shows another alternative embodiment for linking together lancets or test strips 10. They are held in sleeves formed by bonding together two layers of continuous ribbon 60. Although not shown, the continuous ribbon could have an array of holes used to drive the ribbon inside of a cassette arrangement."
>
> "In another embodiment shown in Figure 10A, the lancets are loaded into holders arranged in a continuous belt in the cassette 100. A drive gear 138 drives a rack that opens membrane 122 and contacts the lancet 10. As it moves forward a second membrane 122 is opened creating an opening 124 through which the lancet passes.

Figure 10B shows a section view of integrated lancet with several sections identified. The sensor 220 also shown in Figure 10C . Figure 10C shows an area of the lancet 10 where there is a sensor 220 created by printing or an In Mold Label process. The lancet 10 contains a spring 221 for returning the piercing element 222 to its original position. The piercing element 222 is free to move forward in the lancet, and is returned by the spring 22 1. In use, a pusher engages the lancet at 223 and drives it forward till it contacts the skin. The inertia of 222 continues to move it forward so that it pierces. A sample is drawn into the lancet 10 and contacts the sensor 220. Figure 10 D shows a surface for making electrical contact 224 that is created by a conductive ink that is printed or from an in mold label. The contacting surface 224 is connected to the sensor 220 by small wires or other method."

"Figure 18 shows a integrated lancet and sensor that can be used to take a sample and make a measurement either immediately or transported to another location. It consists of a body 233 that hold a sensor element 232 which could be an in mold label or an assembly after molding. The sensor element 232 has an arrangement of electrodes that can be used to generate an electrical signal that can be measured. The sensor element located around the circumference of body 233. Inside the body a series of disk like elements 231 are placed with channels for transporting the blood from the center, where they are in communication with the piercing element 230 to the outer circumference, where the sensing element 232 is located. The arrangement of the disks and the relative position of the channels can control the amount of sample fluid that is collected. The piercing device in a holder 230 which could be driven by a several different mechanisms passes through the center, piercing the skin and allowing blood to form on the surface with is drawn into the channel by capillary action."

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. **Claims 7 and 10-12** are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The lancet dispensing canister subject matter of the above claims, which were included in the preliminary amendment, were not included in the original filed disclosure, thus constituting new matter.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11. **Claims 6-14** are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Olson et al (US Pub No. 20030211619).

12. In regards to **Claim 6**, Olson et al disclose a canister comprising:

two drums, referred to as “rollers” (118,120) ¶0068, interconnected by a channel, referred to as "throat" (116) (¶0067, 0075), all best seen in Figure 5, the two drums comprising a first and second drum;

multiple strips, referred to as "testers" (4,130a, etc) (¶0043, 0075), are located in the first drum wherein the strips are adhered onto a continuous film, referred to as “strips” (106) ¶0075 or “frame structure" (6) ¶0046, all best seen in Figure 6, wherein the film comprises tractor feed holes (166) along at least one side, best seen in Figure 6 (¶0068);

the tractor feed holes are capable of being driven by a sprocket system in a corresponding meter so that the film moves from the first drum to the second drum (¶0075); and wherein the channel comprises a sufficient area wherein an individual strip is available to have a sample deposited on the strip, best seen in Figure 5-6 (¶0067-0068, 0075).

13. In regards to **Claim** 7, Olson et al disclose a canister comprising:

two drums, referred to as “rollers” (118,120) ¶0068, interconnected by a channel, referred to as "throat" (116) (¶0067, 0075), all best seen in Figure 5, the two drums comprising a first and second drum;

multiple lancets, also referred to as “microneedles” (172) ¶0075, are located in the first drum wherein the strips are adhered onto a continuous film, referred to as “strips” (106) ¶0075 or “frame structure" (6) ¶0046, all best seen in Figure 6, wherein the film comprises tractor feed holes (166) along at least one side, best seen in Figure 6 (¶0068);

the tractor feed holes are capable of being driven by a sprocket system in a corresponding meter so that the film moves from the first drum to the second drum (¶0075); and wherein the channel comprises a sufficient area wherein an individual strip is available to have a sample deposited on the strip, best seen in Figure 5-6 (¶0067-0068, 0075).

14. In regards to **Claims 8, 10**, Olson et al disclose the canister composed of plastic (¶0066), specifically, the cassette (102), which includes drums (118,120) ¶0067, made of plastic. Olson et al also disclose a desiccant material (92) adhered to each strip or tester, which are in contact with said drums during use (Figure 6), to maintain appropriate humidity levels for device functioning (¶0057), wherein such desiccant property is well known in the art as incorporated into materials, such as plastic. Thus, Olson et al disclose at least a portion of said first drum, of a desiccant plastic, an obvious variant of using plastic and a desiccant, for the reasons cited above.

15. In regards to **Claims 9, 11**, Olson et al disclose the sample as blood for blood glucose monitoring (¶0037, 0044).

16. In regards to **Claim 12**, Olson et al disclose the lancet, an integral part of said tester, comprising an in-mold label, referred to as "first conductive layer" (52), comprising an electrically conductive ink (i.e. conductive carbon ink) that forms a pattern of at least one electrical contact (i.e. electrode), best seen in Figure 3 (¶0051).

17. In regards to **Claim 13**, Olson et al disclose the strip or tester comprising an in-mold label, referred to as "first conductive layer" (52), comprising an electrically conductive ink (i.e. conductive carbon ink) and a non-compatible ink, such as “redox reagent system” (54) (¶0051)

or "spacer creating layer" (62) (¶0054), that forms a pattern on a carrier, referred to as "substrate material" (51), best seen in Figure 3.

18. In regards to **Claim 14**, Olson et al disclose the strip as a diagnostic test strip (¶0037).

Conclusion

19. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Freeman et al (US Pub No. 20030083686), Ishizaka et al (US Pat No. 5077010), and Mack Jr et al (US Pat No. 4218421) all disclose test strip or lancet dispensers.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Helen Nguyen whose telephone number is 571-272-8340. The examiner can normally be reached on Monday - Friday, 8 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

HQN
4/12/2006

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